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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/603,665	06/23/2000	Caroline Barry	G-067US03REG	8150
23557	7590	11/21/2005	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			CHUNDURU, SURYAPRABHA	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 11/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/603,665

Applicant(s)

BARRY ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 79-132 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 79-132 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' response to the office action filed on September 1, 2005 has been entered.

Status of the Application

2. Claims 79-132 are pending. Claims 80-86, 95-99, 112-126 are amended. All amendments and arguments have been thoroughly reviewed and deemed persuasive in view of amendment. The rejections made in the previous office action are withdrawn in view of the amendment. The action is made Final necessitated by amendment.

New Grounds of rejections necessitated by amendment

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- A. Claims 80, 82, 121, 123, 129 are rejected under 35 U.S.C. 102(b) as being anticipated by Okano et al. (FEBS Letters, Vol. 391(1,2), page 1-4, 1996).

Okano et al. teach a polypeptide comprising SEQ ID No. 5 as claimed having at least 6 contiguous amino acids, said amino acids span the valine at position 1854 of SEQ ID No. 5 (see citation from Caplus database the Valine at position 1854 of SEQ ID No. 5 comprising span of 6 amino acids corresponding to VMKKEE amino acids of SEQ ID NO. 5). Thus the disclosure of Okano et al. anticipates the instant claims.

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B. Claims 80, 83, 121, 124, 129 are rejected under 35 U.S.C. 102(b) as being anticipated by Eliasof et al. (Vision Research Vol. 38 (10), page 1443-1454, 1998).

Eliasof et al. teach a polypeptide comprising SEQ ID No. 5 as claimed having at least 6 contiguous amino acids, said amino acids span the asparagine at position 1967 of SEQ ID No. 5 (see citation from Caplus database the asparagine at position 1967 of SEQ ID No. 5 comprising span of 6 amino acids corresponding to LNQVNIS amino acids of SEQ ID NO. 5). Thus the disclosure of Eliasof et al. anticipates the instant claims.

C. Claims 80, 82, 121, 123, 129 are rejected under 35 U.S.C. 102(a) as being anticipated by Carninci et al. (Math.Enzymol. , Vol. 101, page 9-44, 1999).

Carninci et al. teach a polypeptide comprising SEQ ID No. 5 as claimed having at least 6 contiguous amino acids, said amino acids span the valine at position 1854 of SEQ ID No. 5 (see sequence alignment from Uniprot database comprising the Valine at position 1854 of SEQ ID No. 5 comprising span of at least 6 amino acids corresponding to VMKKEEL amino acids of SEQ ID NO. 5). Thus the disclosure of Carninci et al. anticipates the instant claims.

4. The following are the rejections made in the previous office action:

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 79-132 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claim 79 is drawn to an isolated polypeptide comprising at least 10 contiguous amino acids shown as positions 1 to 1629 of SEQ ID NO. 5. The instant claim 85 is drawn to a variant polypeptides comprising at least 6 contiguous amino acids of SEQ ID NO. 5. The instant claim 86 is drawn to a composition of isolated polypeptide comprising at least 10 contiguous amino acids of said polypeptide (said 10 contiguous amino acids comprising positions 1-200, 210-400, 401-600, 601-800, 801-1000, 1001-1200, 1201-1400, 1401-1629 of SEQ ID NO. 5). Claims are further drawn to polypeptide fragments comprising at least 20 contiguous amino acids, at least 40 contiguous amino acids, variants and an antibody directed to said fragments. The specification fails to provide structural limitations of said isolated polypeptide fragments comprising at least 10 amino acids. Further the specification fails to provide any information regarding the biological activity of said fragments. The large genus of fragments is represented in the specification by the broad sequence SEQ ID NO. 5. Thus, applicants have expressed possession of only one species in a genus, which comprises hundreds of millions of different possibilities. The written description guidelines note regarding such genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.) With regard to the isolated polypeptide fragments having at least 10 contiguous amino acids, and fragments comprising at

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least 6 contiguous amino acids with specific amino acid substations, it is insufficient to demonstrate identity of regulatory activity in said fragment(s) where no structural information regarding where in the fragment the activity resides. Further no information is given regarding a methodology to determine such common elements or attributes. Further, there is no description of fragments or variants.

With regard to the written description, all of the claims drawn to a large number of polypeptide fragments encompass different structural limitations, for which, no structural limitation is provided in the specification. It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that: "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In this application at the time of filing, there is no record or description, which would demonstrate conception or written description of any biological activity of isolated polypeptide fragments comprising at least 10 contiguous amino acids or variants comprising at least 6 contiguous amino acids.

Response to arguments:

6. With regard to the rejection under 35 USC 112 first paragraph written description, Applicants' arguments and amendment are fully considered and found unpersuasive. Applicants argue that the instant specification supports the chemical structure set for in SEQ ID No. 5 with each of the variant positions and the fragments comprising these positions with a span of at least 6, 8, 10, 20, or 200 amino acids. Applicants also argue that "comprising" format does not mean that the applicants are not in possession of such fragments with variant positions. Examiner notes that the instant specification contains a fragment containing said variants and the instant specification does not support for all possible fragments by permutation and combination comprising these variants. Examiner also notes that any fragment comprising said positions would vary in length from 6 to 200 amino acids and such variants would result in a modified chemical structure, for which the instant specification lacks support. Each of such modified fragment comprising said positions result in an altered protein or unaltered protein comprising said SEQ ID No. 5, Thus the specification lacks support for which of the claimed fragments would function as normal and which of them would function as having altered protein characteristics. The "comprising" open language format of the instant claims would result in many such variants and the scope of such fragments having normal or altered protein function is not described in the instant specification.

Applicants further argue that the instant specification indicates a number of homologs of the claims and refers to page 48-50 for examples of such variants and argue that the specification supports for obtaining such variants. The arguments are fully considered and found unpersuasive. Although the claims are interpreted in the light of the specification, the limitations from the specification cannot be read in to the claims. The claims are drawn to many fragments comprising said variants of SEQ ID NO. 5 and broader in scope and said broad number of

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variants comprising said SEQ ID NO. 5 are not supported by the specification. Therefore the rejection is maintained herein.

7. With regard to the rejection under 35 USC 102(b) as anticipated by Bowcock et al.

Applicants' arguments and amendment are fully considered and the rejection is withdrawn in view of the amendment.

8. With regard to the rejection under 35 USC 102(b) as anticipated by Homburger et al.

Applicants' arguments and amendment are fully considered and the rejection is withdrawn in view of the amendment.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Suryaprabha Chunduru
Patent Examiner
Art Unit 1637


JEFFREY FREDMAN
PRIMARY EXAMINER

11/10/05